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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,126

03/17/2004

James Robert Schwartz

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THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER

ARNOLD, ERNST V

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,126	Applicant(s) SCHWARTZ ET AL.	
	Examiner ERNST ARNOLD	Art Unit 1613	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8,11,12,14,15 and 17-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8,11,12,14,15 and 17-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/11 has been entered.

Claims 1-3, 8, 11, 12, 14, 15 and 17-28 are pending and under examination.

Withdrawn rejections:

Applicant's declaration, amendments and arguments filed 2/17/11 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below is herein withdrawn.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 8, 11, 12, 14, 15, and 17-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhat et al. (WO 96/25913) in view of Gavin et al. (WO 01/00151).

Applicant claims:

- 1) (previously presented) A composition comprising:
 - a) from about 0.01 weight% to about 5 weight%, based on the total weight of the composition, of pyrithione or a polyvalent metal salt of a pyrithione, wherein the pyrithione or polyvalent metal salt of pyrithione is zinc pyrithione;
 - b) from about 0.001 weight% to about 10 weight%, based on the total weight of the composition, of a zinc-containing layered material which provides an augmentation factor greater than 1 wherein the zinc-containing layered material comprises an impurity containing hydroxy-containing basic zinc carbonate and further wherein the ratio of zinc-containing layered material to said pyrithione or a polyvalent metal salt of pyrithione is from about 1:2 to about 3:1.

Determination of the scope and content of the prior art

(MPEP 2141.01)

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Bhat et al. teach compositions comprising monophasic zinc hydroxycarbonate as antimicrobial agent in **personal care products**, such as shampoos, wherein there is a *synergistic action* of **zinc hydroxycarbonate** with detergent and/or anti-**dandruff** actives like **zinc pyrithione** in shampoos/hair dressings (pg. 8, lines 1-18 and claims 1-5 and 7). Thus, the art has already established compositions comprising zinc hydroxycarbonate and zinc pyrithione in personal care products. Bhat et al. further teach personal care product compositions comprising a surfactant and monophasic zinc hydroxycarbonate in an amount of **0.1-20 wt.%** (Claims 1 and 2), wherein the structure of the zinc compound is $\text{Zn}_5(\text{OH})_6(\text{CO}_3)_2 \cdot \text{X} \cdot \text{H}_2\text{O}$, where X varies between 0 and 4 (pg. 6, lines 23-27). When X=0 the same formula for **basic zinc carbonate**, a zinc-containing layered material, as disclosed by Applicants is taught (instant specification pg. 5, lines 16-20), which would intrinsically possess the same **augmentation factor greater than 1** as instantly claimed. From pages 1-2:

35 Basic zinc carbonate may be represented by



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and sometimes it is accompanied with ZnO.

The monophasic zinc hydroxycarbonate of the present invention has the following formula

5



Since Applicant claims the zinc hydroxy carbonate when $X = 0$ (see instant claim 8), then any additional water represents an impurity to the 'pure' composition. The Examiner notes that 'impurities' are not defined in the specification as filed and that in [0033] of the USPGPUB it only teaches that other impurities may be incorporated in the crystal lattice. Therefore, water is interpreted as an impurity. Bhat et al. a method of making a composition by adding zinc hydroxycarbonate to a mixture (pg. 12, lines 1-31).

Bhat et al. teach various methods of making the basic zinc carbonate such as on page 5-6 and claim 6:

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- 25 The process of the present invention for the preparation of zinc hydroxycarbonate, (suitable for use as antimicrobial agent in personal care compositions such as soaps, cosmetic - skin and hair- and dental formulations) comprises
- 30 (i) dissolving a soluble zinc salt, in water and heating it, to keep the solution warm before use,
- (ii) dissolving an alkali metal carbonate, such as sodium potassium or ammonium carbonate, in water,
- 35 (iii) taking water in a precipitation vessel and maintaining it at 35-95 °C,
- (iv) pumping warm solutions of (i) and (ii) into the precipitation vessel simultaneously, and maintaining the temperature at 50-98 °C with continuous stirring and warming if necessary,
- 5 (v) filtering off the precipitate and washing it with water until it is free from anions, and
- (vi) drying the washed material.

It is the Examiner's position that making this basic zinc carbonate intrinsically forms a layered film of an *in-situ* product reaction product because it is the same material as instantly claimed.

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from **0.001 to 10% zinc pyrithione**; from **0.001 to about 10% of a zinc salt** and an anionic deterative surfactant for a topical carrier (Claim 1). Thus if 10% zinc salt

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is present and 1% zinc pyrithione then a ratio of 10:1 is obtained or 10% zinc salt and 3.3% zinc pyrithione for a ratio of about 3:1 or there can be 5% of zinc salt and 10% of zinc pyrithione for a ratio of about 1:2. Gavin et al. disclose aqueous antimicrobial shampoo compositions containing zinc salt and zinc pyrithione and claim a shampoo composition comprising mixtures of zinc carbonate, zinc oxide, zinc hydroxide, cuprous ammonium carbonate, etc... (See examples 3-13 page 57-58 and claim 6). **Methods pertaining to treating microbial infections** preferably related to **dandruff** and treating athlete's foot, a contagious **fungal infection** (Claim 9).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach the amount of zinc pyrithione present; the various 'augmentation factors'; or gallery ions in the zinc-containing layered material. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

2. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach a method for preparing a personal care composition by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound; wherein the molar ratio is between about 1:10 and about 10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step wise generated. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

3. The difference between the instant application and Bhat et al. is that Bhat et al. do not expressly teach a method of treating microbial infections or fungal infections. This deficiency in Bhat et al. is cured by the teachings of Gavin et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Bhat et al. with the amount of zinc pyrithione as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bhat et al. already teach adding zinc pyrithione and Gavin et al provide guidance as to how much to add. The 'augmentation factors' and presence of gallery ions are intrinsic to the composition since the same materials are used by Applicant.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the composition of Bhat et al. with the amount of zinc pyrithione as suggested by Gavin et al. by reacting in a personal care composition comprising zinc pyrithione a carbonate or bicarbonate with a zinc compound; wherein the molar ratio is between about 1:10 and about 10:1; and wherein the zinc pyrithione and the basic zinc carbonate are simultaneously or step wise generated, and produce the instant invention.

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One of ordinary skill in the art would have been motivated to do this because it is merely judicious selection of steps to combine the ingredients by one of ordinary skill in the art. With regard to the amount of carbonate or bicarbonate to add to make the instantly claimed ratios, it is the Examiner's position that the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention. Bhat et al. already teach how to make the basic zinc carbonate and it is merely a design choice to make it *in situ*; step wise or simultaneously in the absence of evidence to the contrary.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the composition of Bhat et al. in a method of treating microbial infections or fungal infections as suggested by Gavin et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Gavin et al. suggest these uses for the composition.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant is asserting that the basic zinc carbonate of Bhat is "without any other impurities" and is thus "monophasic" whereas the instant basic zinc carbonate is "multiphasic" and contains impurities. There are a number of problems with this line of argument. First of all, Applicant does not define what the impurities might be. At best is the description in [0033]:

[0033] Basic zinc carbonate, which also may be referred to commercially as "Zinc Carbonate" or "Zinc Carbonate Basic" or "Zinc Hydroxy Carbonate", is a synthetic version consisting of materials similar to naturally occurring hydrozincite. The idealized stoichiometry is represented by $Zn_5(OH)_6(CO_3)_2$ but the actual stoichiometric ratios can vary slightly and other impurities may be incorporated in the crystal lattice.

The Examiner has asserted that water can be interpreted as an impurity and nothing has been argued against that rationale. Second of all, the impurities suggested by Bhat

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are directed to other mineral deposits as discussed on page 1, lines 23-33 shown below:

zinc hydroxycarbonate occurs in nature in the mineral hydrozincite. Generally sulphide ore bodies are overlain by
25 deposits of smithsonite, calamine and hydrozincite. Franklinite, willemite and zincite occur in white crystalline lime stone in some places. Calcite, dolomite and sometimes quartz occurs as materials associated with zinc blend or sulphide. The monophasic zinc
30 hydroxycarbonate prepared by the process of present invention has a structure similar to that of hydrozincite without any other impurity phases as may be present in the mineral.

Therefore, the "impurity phases" of Bhat are those mentioned above such as calcite, dolomite and calamine. The claims require that an unidentified 'impurity' and not an 'impurity phase' is contained in the hydroxy-containing basic zinc carbonate. So it is perfectly acceptable that the material of Bhat excludes an impurity phase. Bhat does not exclude water or other ions from the monophasic zinc hydroxycarbonate. The Examiner must disagree with Applicant and maintain the position that while Bhat describes a monophasic zinc hydroxycarbonate it still contains 'impurities'. Respectfully, the Examiner does not find this line of argument persuasive.

Applicant next discusses the 1.132 Declaration. The Declaration shows that relationship between relative zinc lability from 3 basic zinc carbonate materials of different origin and reduction of Malassezia where Bruggemann is an impurity containing basic zinc carbonate and the material from Elementis and Cater are without

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any other impurity phases. From Graph 1, it is clear that not all sources of basic zinc carbonate have the same relative zinc lability as the Bruggermann sample is about 57% and the Elementis is about 52% and the Cater sample is about 42% which corresponds to a reduction in Malassezia count IMAC Efficacy of 251.2 to 214.1 to 155.7 respectively. However, there are a couple of issues that need to be addressed. First of all, the 'relative zinc lability' is not a claim limitation but rather an 'augmentation factor' is claimed and nothing has been shown how the samples relate to this 'augmentation factor'. Bhat clearly states that zinc hydroxycarbonate releases zinc ions acting on the skin microflora (page 8, lines 13-16) thus acknowledging that these compounds have a 'relative zinc lability'. In addition, the zinc hydroxycarbonate is available commercially as taught by Applicant in [0032] and available to the ordinary artisan. Essentially, it comes down to judicious selection of known sources of zinc hydroxycarbonate for use in the composition and methods. Applicant has not shown synergistic effects due to the composition per se but only the effects of known commercial products. This is not inventive given the teachings of Bhat because Bhat teach the ordinary artisan to select zinc hydroxycarbonate and that the release of zinc ions is what acts on the microflora and consequently Applicant's declaration data is an expected result. In other words, it is expected that the more zinc released then the better the effect. The ordinary artisan would desire the highest release of zinc ions to obtain the maximum effect. Therefore, selection of the commercially available Bruggemann sample is an obvious choice to the ordinary artisan. Respectfully, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument

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and the present declaration and arguments are not persuasive to overcome the rejection for the reasons discussed above.

Applicant notes the withdrawal of a previous 35 USC 103(a) rejection over Gavin in view of Bhat which was made in the Action filed 4/27/07. In that rejection, Gavin is the primary reference not Bhat as in the present rejection. Thus, the present rejection is different from the prior rejection as the Examiner is relying on different teachings in each respective piece of art and it is not inconsistent to have this current rejection applied and maintained especially when the primary reference of Bhat teaches the desired property of zinc lability in the zinc hydroxycarbonate.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERNST ARNOLD whose telephone number is (571)272-8509. The examiner can normally be reached on M-F 7:15-4:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on 571-272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ernst V Arnold/
Primary Examiner, Art Unit 1613